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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,633	04/20/2001	Gregory A. Demopoulos	OMER117356	2163

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EXAMINER

O HARA, EILEEN B

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/839,633	Applicant(s) DEMOPULOS ET AL.	
	Examiner Eileen O'Hara	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,22,25-39,41 and 44-50 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 20, 22, 25-39, 41 and 44-50 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/15/01, 2/26/02, 7/16/02</u> | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1646

DETAILED ACTION

1. Claims 20, 22, 25-39, 41 and 44-50 are pending in the instant application. Claims 20, 22, 39, 49 and 50 have been amended and claims 21, 23, 24, 40, 42 and 43 have been canceled as requested by Applicant in the Paper filed Nov. 24, 2003.

Election/Restrictions

2. Applicant's election with traverse in part in the Paper filed Nov. 24, 2003 is acknowledged. The traversal is on the ground(s) that the restriction requirement did not include a group for claims to a method and composition of using Human Type II IL-1R, and also that Applicants suggest that the restriction requirement set forth in the Office Action is not warranted in full. During a telephone conversation with Applicants on Oct. 6 and 7, 2003 and in the written response, Applicants suggest a different suitable grouping of four groups as on page 9-10 of the response, which are as follows:

- (I) tumor necrosis factor (TNF) soluble receptors;
- (II) interleukin-1 (IL-1) cytokine soluble receptors;
- (III) class I cytokine soluble receptors; and
- (IV) soluble receptor tyrosine kinases.

If the proposed groups are acceptable, Applicants elect the invention of proposed Group I (TNF soluble receptors), without traverse.

The groups are acceptable, and Group I will be examined on the merits.

Applicant's species election of additional pain/inflammation inhibitory agent, which is cyclooxygenase inhibitors, without traverse, is acknowledged.

Art Unit: 1646

The requirement is still deemed proper and is therefore made FINAL.

All claims are currently under examination.

Priority

3. Applicant is reminded of the following requirement:

In a continuation or divisional application (other than a continued prosecution application filed under 37 CFR 1.53(d)), the first sentence of the specification or application data sheet (37 CFR 1.76) should include a reference to the prior application(s) from which benefit of priority is claimed, and also the status. See 37 CFR 1.78. The status of application 09/072,913 should be updated (now a U.S. Patent No. 6,261,279).

Specification

4.1 The abstract of the disclosure is objected to because it does not recite the specific invention elected, treatment with soluble TNF receptors. Correction is required. See MPEP § 608.01(b).

4.2 The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Method of inhibition of pain and inflammation during surgery comprising administration of soluble TNF receptors.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

Art Unit: 1646

harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 20, 22, 25-39, 41 and 44-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 and 18 of U.S. Patent No. 6261279. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are drawn to a method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering a solution comprising at least one tumor necrosis factor soluble receptor, and solution for that use, and the claims of U.S. Patent No. 6261279 are drawn to a method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering a solution comprising a plurality of pain/inflammation inhibitory agents. Since tumor necrosis factor was well known in the art to cause inflammation, and tumor necrosis factor inhibitors such as soluble receptors were also well known in the art, it would have been *prima facie* obvious to one of ordinary skill in the art to treat a surgical wound with TNF soluble receptors in solution and to prepare such solutions.

Art Unit: 1646

6. The art considered pertinent to the present application is Olmarker, U.S. Patent Application Publication 2003/0176332, which teaches that inhibition of TNF- α by soluble TNF receptors (sections 0028-0030) promotes better wound healing and prevents or reduces scar formation, and that the inhibitor may be applied locally before, during and/or surgery or trauma, and may be applied in an irrigation solution (page 5, section 0124). This is not considered prior art, as the priority date of the instant application preceeds that of the reference, but is cited as being the closest art.

Conclusion

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (571) 272-0871.

Official papers Before Final and After Final filed by RightFax should be directed to (703) 872-9306.

The customer service RightFax number is (703) 872-9305.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Eileen B. O'Hara, Ph.D.

Patent Examiner

A handwritten signature in black ink that reads "Eileen B. O'Hara". The signature is written in a cursive, flowing style.